Complete Summary

GUIDELINE TITLE

Screening for genital herpes: recommendation statement.

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force (USPSTF). Screening for genital herpes: recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2005. 11 p. [32 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously published guideline: U.S. Preventive Services Task Force. Guide to clinical preventive services. 2nd ed. Baltimore (MD): Williams & Wilkins; 1996. Chapter 30, Screening for genital herpes simplex. p. 335-46.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Genital herpes

GUIDELINE CATEGORY

Prevention
Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Clinical Laboratory Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To summarize the U.S. Preventive Services Task Force recommendations on screening for genital herpes and the supporting scientific evidence
- To update the 1996 recommendations contained in the Guide to Clinical Preventive Services, Second Edition

TARGET POPULATION

Asymptomatic adolescents, adults, and pregnant women/neonates seen in primary care settings

INTERVENTIONS AND PRACTICES CONSIDERED

Serological screening tests for genital herpes (e.g., enzyme-linked immunosorbent assay [ELISA], immunoblot, and western blot assay [WBA])

MAJOR OUTCOMES CONSIDERED

- Key question 1a: Does screening for herpes simplex virus (HSV) in asymptomatic adolescents and adults reduce symptomatic recurrences and transmission of disease?
- Key question 1b: Does screening for HSV in pregnant women reduce neonatal HSV and complications?
- Key question 2: Can risk factors identify groups at higher risk for HSV infection?
- Key question 3a: What are the HSV screening tests and their performance characteristics?
- Key question 3b: What is the optimal time to screen during pregnancy?
- Key question 3c: What is the role of screening partners?
- Key question 4: What are the harms of screening?
- Key question 5a: How effective are interventions in reducing symptomatic recurrences and transmission in adolescents and adults?
- Key question 5b: How effective are interventions in reducing neonatal infection and complications?
- Key question 6: What are the harms of interventions?

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A targeted review of the literature was prepared by the Oregon Evidence-based Practice Center (EPC) for the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Companion Documents" field).

MEDLINE was searched from 1996-March 2004 (see Appendix 1 in the original guideline document). References cited in the 2002 report and references suggested by expert reviewers were also included. Captured titles and/or abstracts were downloaded and imported into the EndNote® program to create a library. Titles and/or abstracts were dual reviewed for inclusion or exclusion. Full text papers were retrieved and reviewed using specific inclusion/exclusion criteria.

NUMBER OF SOURCE DOCUMENTS

Seventy-nine full-text articles were obtained and reviewed for the update. Further, a systematic review of antenatal herpes simplex virus (HSV) screening in the United Kingdom was reviewed.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The U.S. Preventive Services Task Force (USPSTF) grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good

Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair

Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor

Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A targeted review of the literature was prepared by the Oregon Evidence-based Practice Center (EPC) for the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Companion Documents" field).

Trials of antiviral therapy were rated for quality by 2 independent reviewers using USPSTF criteria (see Appendix 2 in the companion document titled "Screening for genital herpes: brief update for the U.S. Preventive Services Task Force).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Balance Sheets
Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When the overall quality of the evidence is judged to be good or fair, the U.S. Preventive Services Task Force (USPSTF) proceeds to consider the magnitude of net benefit to be expected from implementation of the preventive service. Determining net benefit requires assessing both the magnitude of benefits and the magnitude of harms and weighing the two.

The USPSTF classifies benefits, harms, and net benefits on a 4-point scale: "substantial," "moderate," "small," and "zero/negative."

"Outcomes tables" (similar to "balance sheets") are the USPSTF's standard resource for estimating the magnitude of benefit. These tables, prepared by the topic teams for use at USPSTF meetings, compare the condition specific outcomes expected for a hypothetical primary care population with and without use of the preventive service. These comparisons may be extended to consider only people of specified age or risk groups or other aspects of implementation. Thus, outcomes tables allow the USPSTF to examine directly how the preventive service affects benefits for various groups.

When evidence on harms is available, the topic teams assess its quality in a manner like that for benefits and include adverse events in the outcomes tables. When few harms data are available, the USPSTF does not assume that harms are small or nonexistent. It recognizes a responsibility to consider which harms are likely and judge their potential frequency and the severity that might ensue from

implementing the service. It uses whatever evidence exists to construct a general confidence interval on the 4-point scale (e.g., substantial, moderate, small, and zero/negative).

Value judgments are involved in using the information in an outcomes table to rate either benefits or harms on the USPSTF's 4-point scale. Value judgments are also needed to weigh benefits against harms to arrive a rating of net benefit.

In making its determinations of net benefit, the USPSTF strives to consider what it believes are the general values of most people. It does this with greater confidence for certain outcomes (e.g., death) about which there is little disagreement about undesirability, but it recognizes that the degree of risk people are willing to accept to avert other outcomes (e.g., cataracts) can vary considerably. When the USPSTF perceives that preferences among individuals vary greatly, and that these variations are sufficient to make trade-off of benefits and harms a "close-call," then it will often assign a C recommendation (see the "Recommendation Rating Scheme" field). This recommendation indicates the decision is likely to be sensitive to individual patient preferences.

The USPSTF uses its assessment of the evidence and magnitude of net benefit to make recommendations. The general principles the USPSTF follows in making recommendations are outlined in Table 5 of the companion document cited below. The USPSTF liaisons on the topic team compose the first drafts of the recommendations and rationale statements, which the full panel then reviews and edits. Recommendations are based on formal voting procedures that include explicit rules for determining the views of the majority.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The USPSTF grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

A

The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

B

The USPSTF recommends that clinicians provide [the service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

C

The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D

The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.

I

The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

COST ANALYSIS

One study found that screening at-risk pregnant women and suppressive therapy in their seropositive partners were more cost-effective interventions (at a cost of $363,000 per case of neonatal infection prevented) compared with no management or cesarean section delivery for women with lesions.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft systematic evidence review to 4 to 6 external experts and to federal agencies and professional and disease-based health organizations with interests in the topic. They ask the experts to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the Task Force in memo form. In this way, the Task Force can consider these external comments and a final version of the systematic review before it votes on its recommendations about the service. Draft recommendations are then circulated for comment from reviewers representing professional societies, voluntary organizations, and Federal agencies. These comments are discussed before the whole USPSTF before final recommendations are confirmed.

Recommendation of Others. Recommendations for screening for genital herpes from the following groups were discussed: the American College of Obstetricians

and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the Centers for Disease Control and Prevention (CDC).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and the quality of the overall evidence for a service (good, fair, poor). The definitions of these grades can be found at the end of the "Major Recommendations" field.

The U.S. Preventive Services Task Force (USPSTF) recommends against routine serological screening for herpes simplex virus (HSV) in asymptomatic pregnant women at any time during pregnancy to prevent neonatal HSV infection. D recommendation

The USPSTF found fair evidence that screening asymptomatic pregnant women using serological screening tests for HSV antibody does not reduce transmission of HSV to newborn infants. Women who develop primary HSV infection during pregnancy have the highest risk for transmitting HSV infection to their infants. Because these women are initially seronegative, serological screening tests for HSV (enzyme-linked immunosorbent assay [ELISA], immunoblot, and western blot assay [WBA]) do not accurately detect those at highest risk. There is no evidence that treating seronegative women decreases risk for neonatal infection. There is limited evidence that the use of antiviral therapy in women with a history of recurrent HSV, or performance of cesarean section in women with active HSV lesions at the time of delivery, decreases neonatal herpes infection. There also is limited evidence of the safety of antiviral therapy in pregnant women and neonates.

The potential harms of screening include false-positive test results, labeling, and anxiety, as well as false negative tests and false reassurance, although these potential harms are not well studied. The USPSTF determined there are no benefits associated with screening, and therefore the potential harms outweigh the benefits.

The USPSTF recommends against routine serological screening for HSV in asymptomatic adolescents and adults. D recommendation

The USPSTF found no evidence that screening asymptomatic adolescents and adults with serological tests for HSV antibody improves health outcomes or symptoms or reduces transmission of disease. There is good evidence that serological screening tests can accurately identify those persons who have been exposed to HSV. There is good evidence that antiviral therapy improves health outcomes in symptomatic persons (e.g., those with multiple recurrences); however, there is no evidence that the use of antiviral therapy improves health outcomes in those with asymptomatic infection. The potential harms of screening include false-positive test results, labeling, and anxiety, although there is limited evidence of any potential harms of either screening or treatment. The USPSTF

determined the benefits of screening are minimal, at best, and the potential harms outweigh the potential benefits.

Clinical Considerations

- Serological screening tests for genital herpes can detect prior infection with HSV in asymptomatic persons, and new type-specific serological tests can differentiate between HSV-1 and HSV-2 exposure (these tests cannot differentiate between oral versus genital herpes exposure); however, given the natural history of genital herpes, there is limited evidence to guide clinical intervention in those asymptomatic persons who have positive serological test results. False-positive test results may lead to labeling and psychological stress without any potential benefit to patients. Negative test results (both false-negative and true-negative results) may provide false reassurance to continue high-risk sexual behaviors.
- There is new, good-quality evidence demonstrating that systemic antiviral therapy effectively reduces viral shedding and recurrences of genital herpes in adolescents and adults with a history of recurrent genital herpes. There are multiple efficacious regimens that may be used to prevent the recurrence of clinical genital herpes.
- The USPSTF did not examine the evidence for the effectiveness of counseling to avoid high-risk sexual behavior in persons with a history of genital herpes to prevent transmission to discordant partners, or for the primary prevention of genital herpes in persons not infected with HSV. There are known health benefits of avoiding high-risk sexual behavior, including prevention of sexually transmitted infections (STIs) and human immunodeficiency virus (HIV) infection.
- Primary HSV infection during pregnancy presents the greatest risk for transmitting infection to the newborn. The fact that women with primary HSV infection are initially seronegative limits the usefulness of screening with antibody tests. The USPSTF did not find any studies testing the use of antibody screening to find and treat seronegative pregnant women (i.e., those at risk for primary HSV infection) prophylactically. However, the number of seronegative pregnant women one would need to treat to theoretically avoid one primary infection would be very high, making the potential benefit small. At the same time, the potential harm to many low-risk women and fetuses from the side effects of antiviral therapy may be great.
- There is fair evidence that antiviral therapy in late pregnancy can reduce HSV recurrence and viral shedding at delivery in women with recurrent HSV infection; however, there is currently no evidence that antiviral use in women with a history of HSV leads to reduced neonatal infection. Likewise, there is limited information on the benefits of screening women in labor for signs of active genital HSV lesions, and for the performance of cesarean delivery on those with lesions.

Definitions:

Strength of Recommendations

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The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

Strength of Evidence

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Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

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Poor

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is identified in the "Major Recommendations" field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate screening for herpes simplex virus

POTENTIAL HARMS

Potential harms of screening for herpes simplex virus-2 (HSV-2) include labeling, anxiety, and disrupting partner relationships. False-positive test results may lead to needless work-up and anxiety. Negative test results may potentially provide false reassurance to continue high-risk sexual behavior.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Recommendations made by the U.S. Preventive Services Task Force are independent of the U.S. Government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder

systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the Agency for Healthcare Research and Quality will make all U.S. Preventive Services Task Force (USPSTF) products available through its Web site. The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access U.S. Preventive Services Task Force materials and adapt them for their local needs. Online access to U.S. Preventive Services Task Force products also opens up new possibilities for the appearance of the annual, pocket-size Guide to Clinical Preventive Services.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Pocket Guide/Reference Cards
Tool Kits

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force (USPSTF). Screening for genital herpes: recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2005. 11 p. [32 references]

ADAPTATION

Not applicable: The guideline is not adapted from another source.

DATE RELEASED

2005 Mar 18

GUIDELINE DEVELOPER(S)

United States Preventive Services Task Force - Independent Expert Panel

SOURCE(S) OF FUNDING

Agency for Healthcare Research and Quality

GUIDELINE COMMITTEE

U.S. Preventive Services Task Force (USPSTF)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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*Members of the USPSTF at the time this recommendation was finalized. For a list of current Task Force members, go to www.ahrq.gov/clinic/uspstfab.htm.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The U.S. Preventive Services Task Force has an explicit policy concerning conflict of interest. All members and evidence-based practice center (EPC) staff disclose at each meeting if they have an important financial conflict for each topic being discussed. Task Force members and EPC staff with conflicts can participate in discussions about evidence, but members abstain from voting on recommendations about the topic in question.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously published guideline: U.S. Preventive Services Task Force. Guide to clinical preventive services. 2nd ed. Baltimore (MD): Williams & Wilkins; 1996. Chapter 30, Screening for genital herpes simplex. p. 335-46.

GUIDELINE AVAILABILITY

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Glass N, Nelson ND, Huffman L. Screening for genital herpes simplex: brief update for the U.S. Preventive Services Task Force. Portland (OR); Agency for Healthcare Research and Quality (AHRQ); 2005. 42 p.

  Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.

Background Articles:

- Woolf SH, Atkins D. The evolving role of prevention in health care: contributions of the U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):13-20.
- Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.
- Saha S, Hoerger TJ, Pignone MP, Teutsch SM, Helfand M, Mandelblatt JS. The art and science of incorporating cost effectiveness into evidence-based recommendations for clinical preventive services. Cost Work Group of the Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):36-43.

The following are also available:

- The guide to clinical preventive services, 2005. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2005. 192 p. Electronic copies available from the AHRQ Web site.

Print copies: Available from the Agency for Healthcare Research and Quality Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

The Interactive Preventive Services Selector tool, which enables users to search USPSTF recommendations by patient age, sex, and pregnancy status, is available as a web-based version or PDA application. It is available from the AHRQ Web site.

PATIENT RESOURCES

The following is available:

- The pocket guide to good health for adults. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2003.

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site. Copies also available in Spanish from the USPSTF Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on June 30, 1998. The information was verified by the guideline developer on December 1, 1998. This NGC summary was updated by ECRI on March 8, 2005. The information was verified by the guideline developer on March 8, 2005.

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Date Modified: 10/9/2006